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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,736	02/04/2004	David Knaack	2004367-0034	5581

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CHOATE, HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

NOTIFICATION DATE	DELIVERY MODE
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01/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary	Application No. 10/771,736	Applicant(s) KNAACK ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 112 is/are rejected.
- 7) ☒ Claim(s) 2 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 6, 2008 has been entered.

Claims 1-31 and 112 are pending in this application.

Applicants' arguments filed November 6, 2008 have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claim 2 is objected to because of the following informalities: the word "calcium carbonite" is misspelled. This assertion is supported by the teaching of the instant

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specification at page 21 wherein the recited bone substitutes are selected from, *inter alia*, calcium carbonate.

Further, when corrected, there will be two occurrences of the word "calcium carbonate" because the word appears again in lines 3-4 of the claim. It is recommended that one occurrence be deleted. . Appropriate correction is required.

Claim 5 is objected to because of the following informalities: the word diisoyanate is misspelled. This assertion is supported by the teaching of the instant specification at least of pages 3, 4 and 5 that recites lysine "diisocyanate". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the polyurethane composite of claim 1 wherein the reinforcement comprises a material selected from the group consisting of calcium carbonite, calcium sulfate, calcium phosphosilicate, sodium phosphate, calcium aluminate, calcium phosphate, calcium carbonate, hydroxyapatite, demineralized bone and combinations thereof". There is insufficient antecedent basis for the term "wherein

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the reinforcement comprises" because claim 1 is drawn to bone and bone substitutes. The materials listed supra are not a subgenus of "bone"; they are only a subgenus of "bone substitute". Amending the claim to recite the polyurethane composite of claim 1 wherein the **bone substitutes** comprise a material selected from the group consisting of ~~calcium carbonate~~, calcium sulfate, calcium phosphosilicate, sodium phosphate, calcium aluminate, calcium phosphate, calcium carbonate, hydroxyapatite, demineralized bone and combinations thereof".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Posnansky U.S. Patent No. 2,882,249, Boyce et al. U.S. Patent No. 6,123,731 and Gunatillake et al. European Cells and Materials 2003.

Posnansky teach the formation of polyurethane with cross-linked bridges (column 2, lines 30-40) by the reaction between a polyisocyanate such as diisocyanate and hydroxy containing monobasic fatty acids (column 1, lines 15-21). It teaches the formation of inter alia, solvent resistant putties (column 2, lines 52-53). Addressing instant claim 5 Posnansky teaches m-tolylene diisocyanate (an alternate chemical name for toluene diisocyanate) as an example of a polyisocyanate that can be employed to make the polyurethane matrix (column 4, lines 54-55). Addressing instant claim 112, drawn to the combination of polyisocyanate with a biomolecule (non hydroxylated), Example 1, column 6 bridging to column 7, teaches linseed oil (not hydroxylated) combined with isocyanate.

It does not teach the addition of a reinforcement embedded in the matrix selected from bone and bone substitutes such as calcium carbonate.

Boyce et al. teach that the use of autograft bone, allograft bone or xenograft bone is well known in both human and veterinary medicine (column 1, lines 15-30) and

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teach the use of said osteoimplants combined with reinforcing particle, fiber, fillers and bone growth inducing substances (column 2, lines 13-17), for example, bioabsorbable polymers (column 4, lines 35-36).

Gunatillake et al. teach biodegradable synthetic polyurethanes for developing scaffolds in tissue engineering (page 1, column 2), formed by a reaction with lysine diisocyanate, (a polyisocyanate) (page 9, column 1). The prepolymers were cross-linked using 2,6 diisocyanatohexate (page 9, column). The prior art employs the same biodegradable synthetic polyurethanes, reacted with lysine diisocyanate, for developing scaffolds in tissue engineering and further comprise the addition of growth factors (page 1, column 2, last paragraph) and Boyce provides motivation to employ bone or bone substitutes with the biodegradable polyurethane scaffold. Gamma caprolactone is disclosed (page 9, column 2) which is a species of polycaprolactone. Regarding instant claims 9 and 10 drawn to further incorporation of bioactive agent, Boyce et al. teach the incorporation of suitable biostatic/biocidal agents (column 4, lines 17-50). The reference is silent regarding amount of reinforcement in the composite; however, the idea of combining reinforcement to composite material was recognized in the art as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to the polyurethane composite that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. The instant claims are drawn to polyurethane wet compressive strength of between 3 MPa and 100 MPa. Gunatillake et al. teach a MPa tensile strength of between 8 to 40 MPa. Gunatillake et al. fail to disclose the MPa tensile

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strength of from 50 to 100 MPa, wet tensile strength, creep rate, degradation rate, maximum shear strength, maximum resolved compressive strength and maximum resolved tensile strength, however, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Response to Arguments

Applicant's arguments, see remarks, filed August 27, 2008, with respect to the rejection(s) of claim(s) 1-31 under 35 USC § 103(a) over Boyce et al. U.S. Patent No. 6,123,731 and Gunatillake et al. European Cells and Materials 2003 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Posnansky U.S. Patent No. 2,882,249, Boyce et al. U.S. Patent No. 6,123,731 and Gunatillake et al. European Cells and Materials 2003. See rejections supra.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

January 13, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

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